Clinical Policy Title:	repository corticotropin
Policy Number:	RxA.158
Drug(s) Applied:	Acthar® Gel
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. West Syndrome (Infantile Spasms) (must meet all)**:**

1. Diagnosis of West syndrome (infantile spasms);
2. Prescribed by or in consultation with a neurologist;
3. Age < 2 years;
4. Diagnosis is confirmed by electroencephalogram;
5. Dose does not exceed 150 units/m^2 per day (divided into twice daily injections of 75 units/m^2).

Approval Duration
Commercial: 3 months
Medicaid: 3 months

B. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;;
4. Prescribed for acute exacerbations of MS;
5. Trial and failure of a recent (within the last 30 days) trial of at least 7-day course of corticosteroid therapy for acute exacerbations of MS, unless contraindicated or clinically significant adverse effects are experienced;
6. Member has been adherent to disease modifying therapy for MS (e.g., Aubagio®, Avonex®, Betaseron®, Copaxone®, Gilenya®, Plegridy®, Rebif®);
7. Dose does not exceed 120 units per day.

Approval Duration
Commercial: 21 days
Medicaid: 21 days

II. Continued Therapy Approval

A. West Syndrome (Infantile Spasms) (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Age < 2 years;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 150 units/m^2 per day (divided into twice

daily injections of 75 units/m^2).

Approval Duration
Commercial: 3 months
Medicaid: 3 months

B. Multiple Sclerosis

1. Re-authorization is not permitted. Acthar® is not indicated for continuous use for this indication. Members must meet the initial approval criteria.

References

1. Berkovich R, Agius M. Mechanisms of action of ACTH in the management of relapsing forms of multiple sclerosis. Ther Adv Neurol Disord. March 2014; 7(2): 83–96. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3932770/. Accessed January 18, 2023.
2. Beck L, Bomback AS, Choi M, et al. KDOQI commentary on the 2012 KDIGO clinical practice guidelines for glomerulonephritis. Am J Kidney Dis. 2013: 62(3): 403-441. Available at: https://kdigo.org/wp-content/uploads/2017/02/KDIGO-GN-GL-Public-Review-Draft_1-June-2020.pdf. Accessed January 18, 2023.
3. Hogan J, Bomback AS, Mehta K, et al. Treatment of idiopathic FSGS with adrenocorticotropic hormone gel. Clin J Am Soc Nephrol. December 6, 2013; 8(12): 2072- 2081. Available at: https://pubmed.ncbi.nlm.nih.gov/24009220/. Accessed January 18, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	1/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was updated to all line of business. 3. Initial and continued therapy approval was updated to include Medicaid approval duration. 4. “Other FDA Approved Indications” section was added to initial approval criteria and continued therapy. 5. Continued therapy criteria II.A.1. & II.C.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…” 6. References were reviewed and updated.	07/1/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy title was updated. 2. Criteria for other FDA approved indications updated. 3. Continued Therapy criteria II.A.1, II.C.1, and II.D.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 4. References were reviewed and updated.	02/25/2021	06/10/2021
Policy was reviewed: 1. Clinical Policy Title: Updated from "repository corticotropin injection" to "repository corticotropin".	01/11/2022	04/18/2022

2. Initial Approval Criteria, I.C and Continued Approval Criteria II.C :Nephrotic Syndrome was removed from PA policy. 3. Continued Therapy Approval Criteria II.A.1, II.C.1 & II.D.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.		
Policy was reviewed: 1. Clinical Policy Title, Drug(s) Applied: Updated from H.P. Acthar® Gel to Acthar® Gel. 2. Initial Approval Criteria, I.A.4: Updated to include new diagnosis confirmation criteria Diagnosis is confirmed by electroencephalogram. 3. Initial Approval Criteria, I.C: Updated to remove approval criteria for Other FDA Approved Indications. 4. Continued Therapy Approval Criteria II.C: Updated to remove approval criteria for Other FDA Approved Indications. 5. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023